

Patients with detectable PSA postprostatectomy should receive more aggressive radiation therapy

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Prostate cancer patients with detectable prostate specific antigen (PSA) following radical prostatectomy should receive earlier, more aggressive radiation therapy treatment, according to a study published in the February 1, 2015 issue of the *International Journal of Radiation Oncology • Biology • Physics* (Red Journal), the official scientific journal of the American Society for Radiation Oncology (ASTRO). This study is a 10-year post-treatment analysis of the German ARO 96-02 trial, a prospective clinical trial that compared a wait-and-see approach versus an adjuvant radiation therapy approach for patients with node negative prostate cancer who had a prostatectomy.

ARO 96-02 accrued 388 patients from 1997 to 2004 with pT3-4pN0 prostate cancer with positive or negative margins who had already undergone radical prostatectomy. Twenty-two centers in Germany participated in the trial. Three patients were excluded from the study because they received immediate hormonal treatment. Prior to reaching an undetectable PSA post-prostatectomy, 159 patients were randomized to a wait-and-see approach (Arm A) and 148 patients were randomized to receive adjuvant radiation therapy (Arm B). Seventy-eight patients who did not achieve an undetectable PSA were moved to Arm C. Four of the patients in Arm C refused treatment, and 74 patients were treated with salvage radiation therapy in Arm C.

All patients in the study had a pre- and post-operative PSA test, a bone



scan and chest radiography. Patients in Arm B received 60 Gy of 3-D conformal radiation therapy. Patients in Arm C received 66 Gy of 3-D conformal radiation therapy. Follow-up was conducted for all eligible patients in the trial quarterly for the first two years, twice a year from three to six years post-treatment, and annually thereafter. The median follow-up time was 112 months (9.3 years).

Of the 74 patients in Arm C, 43 (58 percent) also underwent hormone therapy as a result of recurrence (at the discretion of the attending physician). Seven patients in Arm C, of the 48 who had data available, reached an undetectable PSA after completion of salvage radiation therapy. In Arms A and B, 20 patients (7 percent) experienced distant metastasis, and in Arm C, 12 patients (16 percent) experienced distant metastasis.

Patients with detectable PSA post-prostatectomy (Arm C) experienced limited side effects as a result of <u>radiation therapy</u>. Patients in Arm C did not report any grade 3 or grade 4 acute toxicities. Seven patients experienced severe late effects, with five patients (7 percent) reporting grade 3 bladder impairment, and two patients (3 percent) reporting grade 2 bladder impairment. Fifty patients (68 percent) in Arm C did not report any genitourinary late toxicity, and 59 patients (80 percent) in Arm C did not report any gastrointestinal late toxicity.

Clinical relapse-free survival (cRFS) was calculated using the Kaplan-Meier method. In Arm C, patients had a 10-year cRFS rate of 63 percent. Univariate analysis demonstrated that patients in Arm C who had a Gleason score

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